

REMARKS

Allowed and Allowable Claims

The Applicant thanks the Examiner for the indication that claims 16-21 have been allowed. Claim 52 has been objected to, but has been indicated as allowable if rewritten in independent form. To that end, claim 52 has been rewritten in independent form and allowance of the same is respectfully requested.

Claim Rejections – 35 USC §102 and §103

Claims 15, 22, 23, 39-41, 43-46, 54, 55, 65 and 67 have been rejected under 35 U.S.C. §102(b) as being anticipated by European Patent No. EP 0179695 to Kehr (hereafter “the ‘695 reference”). Additionally, claims 44, 47-51 and 71 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,599,086 to Doty (hereafter “the ‘086 reference”). Claim 42 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the ‘695 reference.

Rejection of Claims 15, 22, 23, 39-41, 43-46, 54, 55, 65 and 67 Based on the ‘695 Reference

With regard to the rejection of claims 15, 22, 23, 39-46, 54, 55, 65 and 67 as being anticipated by the ‘695 reference to Kehr, the Applicant respectfully disagrees with these rejections. On page 2 of the Office Action, the following paragraph is the only reference to the subject matter disclosed in the ‘695 reference to Kehr:

EP 0179695 A1 discloses distraction device (12) comprising an elongate stem (20) having a first end, a second end, a longitudinal axis, a length along the axis, a flange projection outward (15), and a transverse stop element (15, lower end).

Based on the Applicant’s review of the ‘695 reference (in French), it appears that the ‘695 reference discloses a vertebral spacer including an interbody portion 12 having flat upper and lower vertebral engaging surfaces, a pair of oppositely-extending flange portions 15 extending from the interbody portion 12, with each of the flange portions 15 defining a pair of openings for receiving bone screws 14 therethrough for anchoring the implant to the vertebrae.

Independent Claims 22 and 23 and Dependent Claims 15 and 17-20

With regard to the rejection of independent claims 22 and 23 as being anticipated by the '695 reference, independent claims 22 and 23 have been amended to further recite "an elongated driver shaft extending generally along said longitudinal axis and sized to extend outside of the disc space for transmission of said external force to the distraction device". The Applicant has thoroughly reviewed the '695 reference and submits that the '695 reference fails to disclose or suggest such features. The Applicant therefore submits that independent claims 22 and 23, as amended, clearly distinguish over the '695 reference. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 22 and 23 and allowance of the same.

Claims 15 and 17-20 depend from independent claim 23 and are submitted to patentable for at least the reasons supporting the patentability of independent base claim 23. Additionally, further reasons support the patentability of claims 15 and 17-20. For example, claim 15 recites that the elongated stem defines a bore extending between the first and second ends of the stem portion, with the first and second ends extending along the longitudinal axis of the stem portion. Notably, the '695 reference fails to disclose or suggest that the interbody portion 12 has first and second ends defining a longitudinal axis therebetween (see independent claim 23), with the interbody portion 12 defining a bore extending between the first and second ends. Additionally, claim 17 depends from claim 15 and further recites that the bore includes a threaded bore adjacent the first end for receiving a threaded portion of a tool therein, a feature which is clearly not found in the '695 reference. Further, claim 18 recites that the elongated stem has opposite top and bottom portions having a bone engaging surface configured to resist expulsion of the elongated stem from the disc space. Additionally, claim 19 recites that the bone engaging surface of the top and bottom portions includes a plurality of ridges defined thereon, and claim 20 recites that the elongated stem includes side portions between the top and bottom portions, with the side portions each defining an inwardly curved surface. The Applicant submits that the '695 reference fails to disclose or suggest the features recited in claims 15 and 17-20.

Independent Claim 40

Independent claim 40 is directed to a distraction device for distracting an intervertebral space between adjacent vertebrae, and including a stem portion extending along a longitudinal axis and adapted for insertion within the intervertebral space and having a height corresponding to a select distracted height of the intervertebral space and “including opposite bone engaging portions, each of said bone engaging portions defining a plurality of ridges configured to resist expulsion of said stem portion from the intervertebral space”.

The Office Action does not set forth the basis for the rejection of independent claim 40 as being anticipated by the ‘695 reference. In particular, there is no indication in the Office Action regarding any disclosure in the ‘695 reference of a stem portion having opposite bone engaging surfaces that each define “a plurality of ridges” configured to resist expulsion from the intervertebral space. Additionally, the Applicant has reviewed the ‘695 reference and submits that the upper and lower surfaces of the interbody portion 12 are flat (see Figures 1, 2 and 4), and do not define any structure or element that could be construed as comprising a plurality of ridges configured to resist expulsion from an intervertebral space. To the contrary, the interbody portion 12 is held in position within the intervertebral space via bone screws 14 extending through openings in the upper and lower flanges 15, and not via a plurality of ridges extending from upper and lower bone engaging portions of the interbody portion 12. If the rejection of independent claim 40 as being anticipated by the ‘695 reference is maintained, the Applicant respectfully requests that the basis for such rejection be clearly communicated in the next official communication.

Independent Claim 41 and Dependent Claim 51

Independent claim 41 is directed to a distraction device for distracting an intervertebral space between adjacent vertebrae, and has been amended to recite that the stem portion has upper and lower surfaces defining a height corresponding to a select distracted height of the intervertebral space and including side portions that each define “a side surface having a concave curvature extending between said upper and lower surfaces”.

The Office Action does not set forth the basis for the rejection of independent claim 41 as being anticipated by the ‘695 reference. In particular, there is no indication in the Office Action

regarding any disclosure in the '695 reference of a stem portion including side portions, with each of the side portions defining a concave surface. Additionally, the Applicant has reviewed the '695 reference and submits that the side portions of the interbody portion 12 do not define a side surface having a concave curvature extending between upper and lower surfaces of the interbody portion 12. To the contrary, the side portions of the interbody portion 12 are convexly rounded in a circumferential direction (Figures 1 and 3) and are flat in a direction between the upper and lower surfaces of the interbody portion 12. If the rejection of independent claim 41 as being anticipated by the '695 reference is maintained, the Applicant respectfully requests that the basis for such rejection be clearly communicated in the next official communication. Claim 51 depends from independent claim 41 and is submitted to patentable for at least the reasons supporting the patentability of independent base claim 41.

Independent Claims 43 and 44 and Dependent Claims 45-47, 49, 50, 54 and 55

With regard to the rejection of independent claims 43 and 44 as being anticipated by the '695 reference, independent claims 43 and 44 have each been amended to further recite "an elongated driver shaft extending generally along said axis and sized to extend outside of the intervertebral space for application of an external force to the distraction device to transmit said axial force to said one of the adjacent vertebrae". The Applicant has thoroughly reviewed the '695 reference and submits that the '695 reference fails to disclose or suggest such features. The Applicant therefore submits that independent claims 43 and 44, as amended, clearly distinguish over the '695 reference. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 43 and 44 and allowance of the same.

The Applicant notes that dependent claims 47, 49 and 50 have been amended in view of the amendment to independent base claim 44. Additionally, claims 45-47, 49, 50, 54 and 55 depend from independent claim 44 and are submitted to patentable for at least the reasons supporting the patentability of independent base claim 44.

Independent Claim 67 and Dependent Claim 65

Independent claim 67 has been amended to recite a method for performing a surgical procedure on adjacent vertebrae "having a spondylolisthesis condition wherein one of the adjacent vertebrae is anteriorly offset relative to the other of the adjacent vertebrae", providing a

device including an axial stem portion, a transverse flange portion, and a transverse stop portion arranged generally opposite the transverse flange portion, inserting the axial stem portion into an intervertebral space between the adjacent vertebrae, engaging the transverse flange portion against one of the adjacent vertebrae “and transmitting an axial reduction force to the anteriorly offset vertebra to reduce the spondylolisthesis condition”.

The Applicant has reviewed the ‘695 reference and submits that there is no teaching or suggestion of performing a surgical procedure on adjacent vertebrae having a spondylolisthesis condition wherein one of the adjacent vertebrae is anteriorly offset relative to the other. Moreover, there is no teaching or suggestion in the ‘695 reference that the spinal implant is used to reduce a spondylolisthesis condition via engaging a transverse flange portion against an anteriorly offset vertebrae and transmitting an axial reduction force to the anteriorly offset vertebra. To the contrary, the ‘695 reference discloses a spacer including an interbody portion 12 having a pair of flange portions 15 extending from the interbody portion 12 and anchored to the adjacent vertebrae via a number of bone screws 14. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 67 and allowance of the same.

Dependent claim 65 has been amended to recite the steps of “providing the device with an elongated driver shaft extending in an axial direction and sized to extend outside of the intervertebral space” and “applying an external force to the elongate driver shaft resulting in the transmitting of the axial reduction force to the anteriorly offset vertebra to reduce the spondylolisthesis condition.” As indicated above, the ‘695 reference fails to disclose or suggest the inclusion of an elongated driver shaft, much less the step of “applying an external force to the elongated driver shaft resulting in the transmitting of the axial reduction force to the anteriorly offset vertebra to reduce the spondylolisthesis condition.” Accordingly, in addition to the reasons supporting the patentability of independent base claim 67, dependent claim 65 is patentable over the ‘695 reference for additional reasons as well.

Rejection of Claims 44, 47-51 and 71 Based on the '086 Reference

Claims 44, 47-51 and 71 have been rejected as being anticipated by the '086 reference to Doty. As an initial matter, the Applicant notes that claim 51 depends from independent claim 41, which has not been rejected as being anticipated by the '086 reference to Doty. Accordingly, the rejection of dependent claim 51 as being anticipated by the '086 reference appears to be in error, and withdrawal of the same is respectfully requested.

On page 2 of the Office Action, the basis for the rejections of claims 44, 47-51 and 71 as being anticipated by the '086 reference to Doty is set forth as follows:

Doty discloses a surgical instrument (32) comprising an elongated stem (12) having a height, a first end, a second end, a longitudinal axis and a flange (66, upper section) extending outward from the stem and a transverse stop element (66, lower end).

It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989). The Applicant submits that each of the elements and features recited in the rejected independent claims 44, 48 and 71 are not disclosed in the '086 reference, and respectfully requests withdrawal of the rejection of claims 44, 47-51 and 71 for at least the following reasons.

Independent Claim 44 and Dependent Claims 47, 49 and 50

Independent claim 44 is directed to a distraction device for distracting an intervertebral space and recites, among other elements and features, a stem portion adapted for insertion within the intervertebral space, "a transverse flange portion having a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae", "a transverse stop element . . . adapted to engage an opposite one of the adjacent vertebrae to limit insertion of said stem portion into the intervertebral space" and "an elongate driver shaft extending generally along said axis and sized to extend outside of the intervertebral space for application of an external force to the distraction device to transmit said axial force to said one of the adjacent vertebrae".

As an initial matter, independent claim 44 is directed to “a distraction device for distracting an intervertebral space”. However, the spinal stabilization device 10 disclosed in the ‘086 reference comprises an intervertebral prosthesis 12 and a retaining plate 66 which maintains the prosthesis with the intervertebral space. Indeed, there is no teaching or suggestion in the ‘086 references that the stabilization device 10 distracts the intervertebral space. To the contrary, the ‘086 reference teaches that the vertebral bodies are initially distracted apart via “conventional distraction devices (not shown)” such that the prosthesis 12 may be subsequently inserted into the intervertebral space. (Col. 3, lines 27-31).

Additionally, the Office Action refers to element prosthesis 12 as comprising an elongated stem, and that the upper portion of the retaining plate 66 defines a flange and the lower portion of the retaining plate 66 defines a transverse stop element. Even assuming arguendo that the proffered characterization of the prosthesis 12 and the retaining plate 66 is proper, the Applicant submits that the top portion of the retaining plate 66 is not “adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae”, as recited in independent claim 44. To the contrary, the ‘086 reference specifically teaches that the retaining plate 66 is attached to the vertebral bodies 14, 16 via machine screws 68 “after prosthesis 12 has been positioned between the vertebral bodies 14, 16”. (Col. 4, lines 47-52). Accordingly, the upper portion of the retaining plate 66 is not adapted to engage one of the vertebral bodies when the prosthesis 12 is inserted into the intervertebral space to transmit an axial force to the vertebral body, but is instead engaged to the vertebrae subsequent to insertion of the prosthesis 12 into the intervertebral space. Additionally, there is no teaching or suggestion in the ‘086 reference that any portion of the retaining plate 66 transmits an axial force to the vertebral body. Instead, the ‘086 reference teaches that the retaining plate 66 is used to secure the prosthesis 12 in place to prevent posterior migration. (Col. 4, lines 52-53).

Additionally, the Applicant further submits that the lower portion of the retaining plate 66 is not “adapted to engage an opposite one of the adjacent vertebrae to limit insertion of said stem portion into the intervertebral space”, as also recited in independent claim 44. As indicated above, the ‘086 reference specifically teaches that the retaining plate 66 is attached to the

vertebral bodies 14, 16 “after prosthesis 12 has been positioned between the vertebral bodies 14, 16”. (Col. 4, lines 47-52). Accordingly, the lower portion of the retaining plate 66 can not fairly be said to be adapted to limit insertion of the prosthesis 12 into the intervertebral space since the ‘086 reference specifically teaches that the retaining plate 66 is engaged to the vertebrae subsequent to insertion of the prosthesis 12 into the intervertebral space. Further, since the retaining plate 66 is attached to the prosthesis 12 after the prosthesis 12 is inserted into the intervertebral space, the retaining plate 66 does not in any way limit insertion of the prosthesis 12 into the intervertebral space.

For at least the reasons set forth above, the Applicant submits that the ‘086 reference does not teach each and every element and feature recited in independent claim 44. Therefore, the Applicant submits that the rejection of independent claim 44 as being anticipated by the ‘086 reference is improper, and withdrawal of the rejection of independent claim 44 based on the teachings of the ‘086 reference is respectfully requested.

As an initial matter, the Applicant notes that dependent claims 47, 49 and 50 have been amended in view of the amendment to independent base claim 44. The Applicant submits that dependent claims 47, 49 and 50 are patentable for at least the reasons supporting the patentability of independent base claim 44. Additionally, further reasons support the patentability of dependent claims 49 and 50. For example, claim 50 recites that “said elongated driver shaft is threadedly engaged with said stem portion”. Even assuming arguendo that the wrench 32 comprises an insertion tool, and that the prosthesis 12 comprises a stem portion, the wrench 32 is clearly not in any way “threadedly engaged” with the prosthesis 12. Indeed, the only contact between the wrench 32 and the prosthesis 12 is the engagement of the gear head 34 with the gear teeth 26 on the pins 20. However, the intermeshing engagement between the gear head 34 and the gear teeth 26 clearly does not constitute threading engagement, and the ‘086 reference fails to even suggest threading engagement between any portion of the wrench 32 and the prosthesis 12.

Independent Claim 48

Independent claim 48 is directed to a distraction device for distracting an intervertebral space and recites, among other elements and features, a stem portion adapted for insertion within the intervertebral space and having a height corresponding to a select distracted height of the

intervertebral space, “a transverse flange portion having a bone contacting face adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae”, and an insertion tool engaged with the stem portion and sized to extend outside of the intervertebral space for transmission of the axial force to the adjacent vertebrae, with “said flange portion formed integral with said insertion tool”.

The Office Action refers to wrench 32 as comprising a surgical instrument, the prosthesis 12 as comprising an elongate stem 12, and the upper portion of the retaining plate 66 as comprising a transverse flange portion. Even assuming arguendo that the proffered characterization of the wrench 32, the prosthesis 12, and the retaining plate 66 is proper, the Applicant submits that the ‘086 reference fails to disclose each of the features recited in independent claim 48 for at least the following reasons.

As an initial matter, independent claim 48 is directed to “a distraction device for distracting an intervertebral space”. However, as indicated above, the spinal stabilization device 10 disclosed in the ‘086 reference comprises an intervertebral prosthesis 12 and a retaining plate 66 which maintains the prosthesis with the intervertebral space. Additionally, there is no teaching or suggestion in the ‘086 references that the stabilization device 10 distracts the intervertebral space. To the contrary, the ‘086 reference teaches that the vertebral bodies are initially distracted apart via “conventional distraction devices (not shown)” such that the prosthesis may be subsequently inserted into the intervertebral space. (Col. 3, lines 27-31).

Additionally, the top portion of the retaining plate 66 does not comprise a transverse flange portion that is “adapted to engage one of the adjacent vertebrae when said stem portion is inserted into the intervertebral space to transmit an axial force to said one of the adjacent vertebrae”, as recited in independent claim 48. To the contrary, as indicated above with regard to independent claim 44, the ‘086 reference specifically teaches that the retaining plate 66 is attached to the vertebral bodies 14, 16 “after prosthesis 12 has been positioned between the vertebral bodies 14, 16”. (Col. 4, lines 47-52). Accordingly, the upper portion of the retaining plate 66 is not adapted to engage one of the vertebral bodies when the prosthesis 12 is inserted into the intervertebral space to transmit an axial force to the vertebral body, but is instead

engaged to the vertebrae subsequent to insertion of the prosthesis 12 into the intervertebral space. Additionally, there is no teaching or suggestion in the '086 reference that any portion of the retaining plate 66 transmits an axial force to the vertebral body. Instead, the '086 reference teaches that the retaining plate 66 is used to secure the prosthesis 12 in place to prevent posterior migration. (Col. 4, lines 52-53).

The Applicant further submits that even assuming *arguendo* that the wrench 32 comprises a surgical instrument, and that the upper portion of the retaining plate 66 comprises a transverse flange portion, the upper portion of the retaining plate 66 is not "formed integral with" the wrench 32, as recited in independent claim 48. To the contrary, the wrench 32 and the retaining plate 66 comprise individual components that are formed separately from one another. Indeed, as illustrated in Figure 7, the retaining plate 66 defines an opening for passage of the gear head 34 therethrough for engagement with the gear teeth 26 on the pins 20. The wrench 32 does not even appear to come into significant contact with the retaining plate 66, much less being formed integral therewith, as recited in independent claim 48. Moreover, the wrench 32 does not transmit an axial force to a vertebra via a transverse flange portion, as substantially recited in independent claim 48. Instead, the wrench 32 is used to transmit a transverse force to the pins 20 via rotation of the gear head 34. As indicated above, the wrench 32 does not even appear to come into significant contact with the retaining plate 66, much less transmit an axial force to a vertebra via the retaining plate 66.

For at least the reasons set forth above, the Applicant submits that the '086 reference does not teach each and every element and feature recited in independent claim 48. Therefore, the Applicant submits that the rejection of independent claim 48 as being anticipated by the '086 reference is improper, and withdrawal of the rejection of independent claim 48 based on the teachings of the '086 reference is respectfully requested.

Independent Claim 71

Independent claim 71 is directed to a method for performing a surgical procedure on adjacent vertebrae and recites, among other steps and features, providing a device including an axial stem portion and a transverse flange portion, the axial stem portion configured for selective engagement with a surgical instrument, inserting the axial stem portion into an intervertebral

space between the adjacent vertebrae, engaging the transverse flange portion against one of the adjacent vertebrae, selectively engaging the surgical instrument with the axial stem portion, with “the surgical instrument comprising a tubular sleeve”, and reciting the step of “advancing a surgical device through the tubular sleeve toward the intervertebral space”.

The Office Action does not set forth the basis for the rejection of independent method claim 71 as being anticipated by the ‘086 reference. In particular, there is no indication in the Office Action regarding any disclosure in the ‘086 reference that teaches the steps of “selectively engaging” a surgical instrument “comprising a tubular sleeve” with an axial stem portion, and “advancing a surgical device through the tubular sleeve toward the intervertebral space”. Indeed, the Office Action does not make reference to any element in the ‘086 patent that corresponds to a tubular sleeve which is engaged to an axial stem portion, nor does the Office Action make reference to an element that corresponds to a surgical device which is advanced through a tubular sleeve. Additionally, the Applicant has thoroughly reviewed the ‘086 reference and can find no reference whatsoever to engaging “a tubular sleeve” with an axial stem portion, and “advancing a surgical device through the tubular sleeve toward the intervertebral space”. If the rejection of independent claim 71 as being anticipated by the ‘086 reference is maintained, the Applicant respectfully requests that the basis for such rejection be communicated in the next official communication.

CONCLUSION

In view of the foregoing remarks, it is respectfully submitted that the Applicant's application is in condition for allowance with pending claims 15-23, 39-52, 54, 55, 65, 67 and 71.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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